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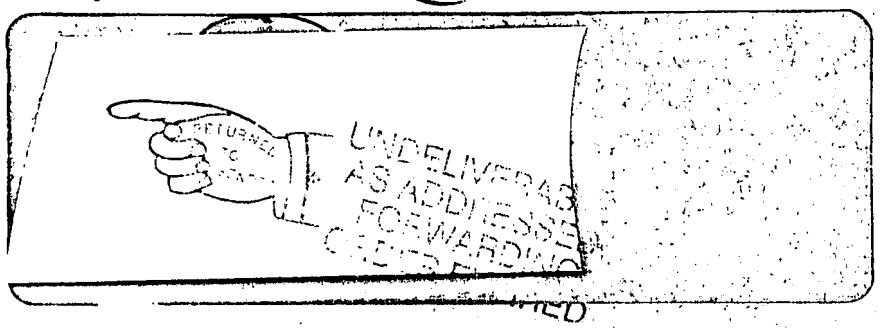

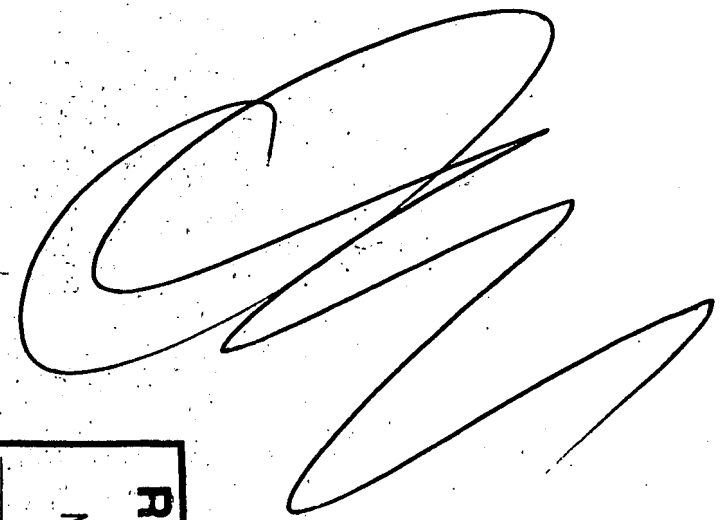

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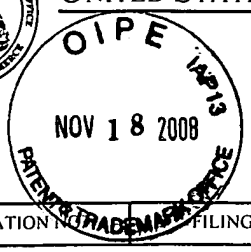

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,291	03/02/2004	James H. Coombs	NAGACO.074A	3167

7590 10/27/2008

Donald Bollella
DB Technical Consulting
126 Almador
Irvine, CA 92614

EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
10/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/792,291	COOMBS ET AL.	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 22-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-21 and 55-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/15, 8/3, 1/8*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group IV, claims 15-21, in the reply filed on 25 July 2008 is acknowledged. New claims 55-66 also read on this group and are examined on the merits.

Claims 1-14 and 22-54 have been withdrawn.

Claim Objections

2. Claim 66 is objected to because of the following informalities: the claim contains duplicate punctuation at the end of the claim. Only one "." should be present. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Sheppard, Jr. et al. (US 6,143,247).

Sheppard, Jr. et al. teach an optical bio-disc comprising: a substantially circular substrate having a center and an outer edge (col. 10, lines 21-25); an active layer associated with the substrate (detection chamber has porous filter, col. 15, lines 8-11); a target zone disposed between the center and the outer edge (detection chamber is on platform, and is therefore between center and outer edge, col. 10, lines 32-34); and a

plurality of capture antibodies bound to the active layer such that the antibodies are immobilized on the active layer in the target zone (detection chamber coated with specific binding reagent, col. 6, lines 13-21; specific binding reagent may be antibodies, col. 10, lines 32-42; specific binding reagents are immobilized on the porous filter, col. 15, lines 5-11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al. (US 6,143,247) in view of Tachikawa et al. (US 2002/0187510).

Sheppard, Jr. et al. teach an active layer that is a filter associated with the substrate in the detection chamber, but fail to teach the porous filter material being nitrocellulose.

Tachikawa et al. teach a porous filter having immobilized antibodies, wherein the porous filter is nitrocellulose (par. 142), in order to provide a porous material that supports a ligand for a target analyte.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the porous filter layer in the bio-disc of Sheppard, Jr. et al., nitrocellulose as taught by Tachikawa et al., in order to provide a material on which a ligand for a target analyte is easily immobilized.

With respect to claim 17, Sheppard, Jr. et al. teach the substrate including encoded information associated therewith and encoded information being readable by a disc drive assembly to control the rotation of the bio-disc (col. 27, lines 24-31 and lines 42-46).

Regarding claim 18, Sheppard, Jr. et al. teach the bio-disc further comprising a reflective layer formed on a surface of the substrate (col. 10, line 64-col. 11, line 2; col. 16, line 43-col. 17, line 19).

With respect to claims 19 and 20, Sheppard, Jr. et al. teach a flow channel in fluid communication with the target zone and an input site in fluid communication with the flow channel (input means connected to detection chamber on surface platform, col. 5, lines 58-67; chambers on platform are in fluid communication with each other which indicates the presence of a flow channel, col. 12, lines 36-48; flow channel is capillary, col. 8, lines 26-40; Fig. 3A-3C) and an enzyme that when exposed to an enzyme substrate produces a signal (col. 6, lines 48-60) detectable by an incident beam of electromagnetic radiation (col. 22, lines 53-60).

5. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al. (US 6,143,247) in view of Tachikawa et al. (US 2002/0187510), as applied to claim 19, further in view of Christopherson et al. (US 2002/0019018).

Sheppard, Jr. et al. in view of Tachikawa et al. teach a plurality of capture antibodies immobilized on the bio disc, but fail to teach the plurality of capture antibodies having an affinity to a common surface marker on cells.

Christopherson et al. teach a target zone having a plurality of immobilized capture antibodies (par. 16, plurality of immunoglobulins immobilized in a discrete antibody spot, par. 142), wherein the capture antibodies in a single zone have an affinity to a common surface marker on cells (antibodies immobilized in a single discrete spot are directed to the same single epitope on an antigen, par. 142; antibodies may be directed to a surface marker on cells, par. 58), in order to detect the presence of cancer or a propensity to develop cancer.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the optical bio disc of Sheppard, Jr. et al. in view of Tachikawa et al., a plurality of capture antibodies in a single target zone having an affinity to common surface maker on cells as taught by Christopherson et al. because Sheppard, Jr. et al. is generic with respect to the antibodies that can be immobilized in the target zone and one would be motivated to use the appropriate antibodies for detection of the desired analyte.

6. Claims 55-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al. (US 6,143,247), as applied to claim 15, in view of Christopherson et al. (US 2002/0019018).

Sheppard, Jr. et al. teach a plurality of capture antibodies immobilized on the bio disc, wherein the plurality comprises populations of antibodies, each population having an affinity to a different analyte (col. 11, lines 9-12), but fail to teach the plurality of capture antibodies having an affinity to different cell surface markers.

Christopherson et al. teach a plurality of target zones each having a population of immobilized capture antibodies (par. 16, plurality of immunoglobulins immobilized in a discrete antibody spot, par. 142; plurality of spots each having a population "P" of capture antibodies, par. 123), wherein each antibody population has an affinity to a different cell surface marker (antibodies immobilized in different discrete spots are directed to the different cell surface antigens, par. 123 and 212), and with respect to claim 61, Christopherson et al. also teach that a plurality of capture antibodies may comprise a single population of antibodies that have an affinity to a single cell surface marker (plurality of antibodies in each discrete spot may have an affinity to the same epitope, which would be a single cell surface marker, par. 143 and 58), in order to detect the presence of cancer or a propensity to develop cancer.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the optical bio disc of Sheppard, Jr. et al., a plurality of populations of capture antibodies in target zones having affinities to different surface maker on cells as taught by Christopherson et al. because Sheppard, Jr. et al.

is generic with respect to the antibodies that can be immobilized in the target zone and one would be motivated to use the appropriate antibodies for detection of the desired analyte.

With respect to claims 56-58 and 61-64, Christopherson et al. teach that cells bound to antibodies from at least one population of antibodies (lymphoma cells bound to antibodies in discrete spots, Fig. 5 and par. 92; par. 221), wherein the cells are lymphocyte blood cells (par. 111 and 169), in order to detect the presence of cancer or a propensity to develop cancer.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the optical bio disc of Sheppard, Jr. et al., lymphocyte blood cells bound to capture antibodies as taught by Christopherson et al., in order to provide an assay device that detects cancer in blood samples.

Regarding claims 59, 60, 65 and 66, Sheppard, Jr. et al. teach all cells attached to beads (cells to be detected are mixed and attached to gold nanoparticles, which are beads, for labeling purposes, col. 15, lines 20-34).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Primary Examiner, Art Unit 1641

Notice of References Cited	Application/Control No. 10/792,291	Applicant(s)/Patent Under Reexamination COOMBS ET AL.	
	Examiner MELANIE YU	Art Unit 1641	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2002/0019018	02-2002	Christopherson et al.	435/7.23
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	10/792,291
	Filing Date	March 2, 2004
	First Named Inventor	James Coombs
	Art Unit	1645
(Multiple sheets used when necessary)	Examiner	Not Yet Assigned
SHEET 1 OF 3	Attorney Docket No.	NAGACO.074A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
/MY/	1	20020151043	10.17.2002	Gordon	
	2	20020122364	09.05.2002	Worthington et al.	
	3	20030133840	07.17.2003	Coombs et al.	
	4	20030082568	05.01.2003	Phan et al.	
	5	20030104486	06.05.2003	Selvan	
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	26	20020151043	10.17.2002	Gordon	
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	28	20020172980	11.21.2002	Phan et al.	
/MY/	29	20020168663	11.14.2002	Phan et al.	

Examiner Signature	/Melanie Yu/ (01/08/2008)	Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	31	20020098528	07.25.2002	Gordon et al.	
	32	20020196435	12.26.2002	Cohen et al.	
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NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
/MY/	45	U.S. Patent Application 10/347,119, filed January 17, 2003 (Atty Docket No. NAGACO.029A). See file wrapper image.	
	46	U.S. Patent Application 10/351,604, filed January 23, 2003 (Atty Docket No. NAGACO.031A). See file wrapper image.	
	47	U.S. Patent Application 10/351,244, filed January 24, 2003 (Atty Docket No. NAGACO.033A). See file wrapper image.	
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/MY/	50	U.S. Patent Application 09/643,106, filed August 21, 2000 (Atty Docket No. NAGACO.068A). See file image wrapper.	

Examiner Signature	/Melanie Yu/ (01/08/2008)	Date Considered

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/MY/	51	International Search Report from PCT Application No PCT/IB2004/002780, mailed April 14, 2005	

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Examiner Signature	/Melanie Yu/ (01/08/2008)	Date Considered

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	10/792,291
	Filing Date	March 2, 2004
	First Named Inventor	James Coombs
	Art Unit	1641
(Multiple sheets used when necessary)	Examiner	Yu, Melanie J
SHEET 1 OF 1	Attorney Docket No.	NAGACO.074A

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